PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Tracy E. Grim, et al.	Examiner:	Marie Patterson
Serial No.	09/592,462	Group Art Unit:	3728
Filed:	June 9, 2000	Docket No.	480032-307
Title:	FOOTGEAR WITH PRESSURE RELIEF ZONES		

CERTIFICATE UNDER 37 CFR 1.8
I hereby certify that this correspondence and identified enclosures are being deposited with the United States Postal Service, first class mail, postage prepaid, under 37 C.F.R. 1.8 on the date indicated, and is addressed to the Commissioner for Patents, BOX: Non-Fee Amendment, Washington, D.C. 20231 on October 9, 2001

Justina S. Townsend

BOX: Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF TRACY E. GRIM

I, TRACY E. GRIM, hereby declare as follows:

1. I am one of the inventors in the above-identified patent application.

2. I served in the U.S. Navy for four years, and I was a hospital corpsman for three and one-half years of this period. I attended an initial Navy course of training for hospital corpsmen, and subsequently attended a more advanced specialty navy school for orthopedic training, a three year course known in the U.S. Navy as the 8489 training program, which I completed in 1977. For three years, I was employed by the Campbell Clinic, located in Memphis, Tennessee, as an Orthopedic Physician's Surgical Assistant (O.P.A.), and during this period of time I was responsible for all of the fracture immobilization, and associated casting of injured limbs for about 24 Orthopedic surgeons. Later, for about four or five years I was employed by Carapace, Inc., and traveled on behalf of this company throughout the United

States and in a number of foreign countries, lecturing on fracture bracing, and performing demonstrations, using, among other equipment, Carapace products.

3. About twelve years ago I started independent consulting work, and at present I am devoting most of my time in this capacity to the affairs of Royce Medical, the assignee of the above-identified patent application.

4. I have reviewed the communication from the U.S. Patent and Trademark Office dated July 10, 2001 and all of the references cited in that communication, including A. C. Andres U.S. Patent No. 4,793,078, (the –078 patent), D. Kellerman U.S. Patent No. 5,154,682 (the –682 patent) and Y. Moronaga et al. U.S. Patent No. 4,633,598 (-598 patent).

5. Initially, attention is directed to Exhibits A through D which are medical papers discussing ulcers, particularly as related to diabetic ulcers. In these papers, particular attention is directed to Exhibit B, involving research supported by a grant by Royce Medical, the assignee of the present application. This article clearly brings out the advantages and superiority of the present invention, as compared with the other principal proposed arrangements for treating diabetic ulcers.

6. The –078 patent clearly has limitations in that the pressure relief is only allowed in specific areas, and will only accommodate specific sized ulcers. Should an ulcer lie on the edge, or outside of these specific zones, then the pad will become useless from pressure relief function. It is noted that the –078 patent states that "the number, shape and position of the depressions 18 and 18a may be chosen as best suited to the needs of most users", and "Portions may be cut from this insert 19b or it may be cut into pieces to suite the users' requirements". This –078 device obviously was a step in the right direction, but it clearly does not have the advantages of a full grid or array or removable elements. Our present invention with the full grid means that the product can be used to accommodate ulcers anyplace on the foot. Further, at a later date, when a new ulcer or ulcers appear at a different location, the same footgear may be used merely by reinserting the previously removed elements and removing new elements in the grid at a different location. With the specifically located recesses of the –078 patent, this flexibility and versatility is not present.

7. Considering the Andrews –078 patent from a somewhat different perspective, it involves an insole II and recesses or depressions 18 in fixed locations, which may be filled with inserts 19. Our construction, on the other hand involves an array of resilient elements underlying

the entire sole area of the foot. In actual practice, consider how the Andrews –078 device would be marketed. Presumably the manufacturer would make insoles with fixed location recesses as shown in the –078 patent drawings. The doctor treating a patient would remove inserts matching the ulcers on a patients foot. But what happens when the ulcer is not in the exact location of the depressions of the Andrews –078 structure? The doctor would possibly send back to the manufacturer and ask for a new special insole, or the doctor might try to cut the insole in a makeshift way to create a new recess. And similarly, what happens when the ulcer increases in size or decreases in size? Again the Andrews –078 structure with its fixed location depressions or recesses cannot handle the problem. However, our structure readily accommodates both of these problems by having the full array of removable and reinsertable resilient elements. Ulcers anyplace on the foot may be accommodated. If the ulcer increases or decreases in size additional elements may be added or removed. If the ulcer is under the instep or in any location whatsoever, our orthopaedic device can accommodate the situation without the need to go back to the manufacturer for a new device. This structure with these enumerated advantages is not shown or suggested by the Andrews –078 patent.

8. The –682 patent has many limitations regarding its function for the treatment of plantar ulcerations. The primary limitation is that there is no way to completely relieve the pressure under the ulcer site, and this is a requirement for healing these conditions. While the '682 patent can provide pressure "reduction", the continuous layer next to the skin will always provide some pressure and tension on the skin of the foot. This constant pressure and tension can lead to the deformation of fragile skin and closing of the super-thin capillaries located in the skin and fat tissue in the wound area, thereby reducing or eliminating capillary refill and venous return, both of which are critical to the regeneration and replacement of damaged and necrotic tissue.

9. The reason we shift around at night is due in fact to an autonomic reaction designed to prevent this very issue from occurring to even healthy tissue while we sleep. Our nervous system tells us to shift in our sleep, allowing capillary refill in the skin areas that were bearing weight. If we did not move, then we would get pressure sores in those areas. The people that this –682 product is designed to treat already have systemic problems that limit blood flow to their feet (diabetes, vascular problems, etc.) so a product that would in anyway hinder that flow would be detrimental to the situation. In addition, the feet are the farthest areas on the

human body from the heart, making venus return from the feet taxing even in a healthy person, requiring a strong blood pressure to ensure good function, That is why in traditional treatment modalities, complete weight/tension removal has provided the best results, even to the extreme of putting the patient in bed or a wheelchair to eliminate the pressure. (See the attached studies and information for further description of the pressures associated with the foot, ailments, and treatment methods).

10. Another shortcoming of the –682 patent is the low coefficient of friction next to the foot. This would enable the foot to slip and slide within the footgear, causing unnecessary pressure in the toe, sidewalls and heel during the gait cycle, possibly causing new pressure sores or blisters in those areas.

11. The mobility of the removable sections under the smooth top surface is yet another limitation that makes the –682 device unsultable for the treatment of plantar ulcers. These sections cannot move independently under the skin as they are all attached to the surface that is in contact with the skin. Our product which has sections connected on the shoe side of the insole, allows for some independent movement of these sections next to the skin, thereby accommodating the hills and valleys of the traumatized or diseased foot to a much higher extent.

12. In progressive stages of the vascular compromised patient, the bones of the foot actually begin to collapse in the areas of highest stress (i.e., arches fall, metatarsal heads collapse, etc.) until the profile of the normal smooth bottomed foot becomes synonymous to stair steps and even the bottom of ice cream cones! Because a continuous film, as described in the –682 patent, would certainly have varying degrees of tension depending on how many steps are involved, the design will certainly create peak pressures and tension surrounding and supporting the deepest areas of bony infringement. In our invention, the surface is cut into multiple independent small supportive pillars. These pillars can support the bony prominences of the deformed foot with small independent movements that are not restricted by the tensions of a continuous film, no matter how stretchable or flexible that film is. The micro-motion allowed by these independent pillars reduces both peak pressures and shear forces, both of which are very important in the treatment of the involved "craterous" profile of many patient's feet in the advanced stages of disease.

13. The shape and size of the sections in our product allow for more precise removal of pressure for smaller ulcers, as compared to the larger sections shown and described in the –682 patent.

14. The attached written materials presented as Exhibits A-D bring out the serious nature of diabetic ulcers on the feet, and the fact that improperly treated ulcers often lead to amputation. Where such drastic results may result from improper treatment, a fully appropriate treatment with full relief in the ulcerated area is essential. In Exhbit B attached hereto, a medical study funded by Royce Medical, the assignee of this application, the product of the present invention is compared with the best known available alternative arrangements. As indicated in the graphs and test results, the product of the present invention is superior to the other principal methods or devices, except for casts, which obviously have other problems including access to inspect the foot, for example. It is further noted that the device of the –078 patent lacks the flexibility and versatility, as well as capability for re-use for ulcers in different locations, provided by our invention. In addition, the –682 with its direct contact with the foot clearly has serious shortcomings as discussed above.

15. In closing, it is submitted that the present invention is clearly superior and is unobvious to those skilled in the art, as compared with all other known alternatives.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent application issuing thereon.

Respectfully submitted,

Date: Sept 10'01

Tracy E. Grim